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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/599,344

09/26/2006

John L. Beiswenger

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BARLEY SNYDER, LLC

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EXAMINER

SORIANO, BOBBY GILES

ART UNIT

PAPER NUMBER

3769

NOTIFICATION DATE

DELIVERY MODE

06/03/2010

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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<b>Office Action Summary</b>	<b>Application No.</b> 10/599,344	<b>Applicant(s)</b> BEISWENGER ET AL.	
	<b>Examiner</b> Bobby Soriano	<b>Art Unit</b> 3769	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 17 February 2010.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) 1-9 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 10-20 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 15 June 2008 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)         | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)         | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

The Examiner acknowledges the amendment filed on February 17, 2010, wherein claims 10-20 are pending.

#### ***Response to Arguments***

Applicant's arguments with respect to claims 10-12 have been considered but are moot in view of the new grounds of rejection.

#### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

**Claims 10-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ross et al. US Patent Application 2004/0186390 (hereinafter “Ross”) in view of Williams et al. US Patent Number 4,294,262 (hereinafter “Williams”), further in view of Lee et al. US Patent Application 2005/0094707 (hereinafter “Lee”), and further in view of Lovejoy et al. US Patent Application 2002/0087057 (hereinafter “Lovejoy”).**

Ross discloses a mouthpiece apparatus for measuring a plurality of physiological signals. The apparatus comprises a mouthpiece positioned in line with a fluid channel consisting of ultrasonic transducers for measuring peak flow through the fluid channel (Ross Figs. 23 and 24 as described in paragraphs [0114] – [0121]; note that in paragraph [0009] and [0060] that the

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mouthpiece, fluid channel, and respiratory analyzer are considered one unitary structure). The apparatus also comprises memory for storing acquired physiological parameters (Ross Fig. 1F memory 80 as disclosed in paragraph [0051] and [0152]). Ross further discloses other suitable forms of determining respiratory flow including thermal methods, pitot tubes, and *turbines* (Ross paragraph [0131]), but is silent on using magnetic impellers with a field-effect transistor counting the number of rotations per second of the impellor. However Williams, a reference in an analogous art, discloses such a method of analyzing respiratory performance using a rotary turbine with attached magnets and wherein rotation is calculated relative to respiratory flow (Williams Fig. 2 as described in column 1 lines 46-56 and column 3 lines 8-22). Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to substitute the ultrasonic transducers of Ross with the magnetic rotary turbines as disclosed in Williams, because Williams discloses magnetic rotary turbines as improved turbine methods of detecting respiratory flow capable of isolating respiratory flow from mechanical noise of rotary mechanisms (Williams column 1 lines 32-42).

Modified Ross discloses that additional physiological sensors can be attached within the mouthpiece to obtain other biological system conditions such as cardiac output using temperature and blood pH sensitivity (Ross paragraphs [0126] and [0176] – [0188]), but is silent on the types of sensors used as claimed by the Applicant to obtain these parameters. However Lee, a reference in an analogous art, discloses an electronic thermometer probe with a metallic tip used for placing in a subject's oral cavity to obtain temperature readings (Lee Figs. 5A and 5B as disclosed in paragraphs [0018] and [0020] - [0022]; the probe as being capable of being placed in a subject's oral cavity would therefore be capable of being placed under the subject's tongue). Therefore it would have been obvious to one of ordinary skill in the art at the time of the

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invention to substitute the means of obtaining temperature for cardiac output as disclosed in Ross with an electronic thermometer probe as disclosed in Lee, because Lee teaches such electronic probes with metallic tips are faster, safer, and more efficient than conventional thermometer probes (Lee paragraph [0005]).

Modified Ross in view of Williams and Lee teaches obtaining blood pH levels for determining cardiac output, but does not teach a secondary probe with a metallic tip disposed in the mouthpiece for measuring saliva acidity. However Lovejoy, another reference in an analogous art, discloses a probe for measuring pH levels in the mouth located underneath the user's tongue to noninvasively detect levels of perfusion failure related to blood flow (Figs. 1 and 8 paragraphs [0008] and [0050]; [0036] indicates metal contacts). Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the cardiac output configuration disclosed in Ross with the pH probe as disclosed in Lovejoy, because Lovejoy discloses such a probe as being noninvasive (capable of determining pH levels from saliva as opposed from the blood) and still be capable of detecting blood perfusion failure that could indicate early signs of patient condition deterioration (Lovejoy paragraph [0008]).

The Examiner concedes that the applied references of Ross, Williams, Lee, and Lovejoy do not specifically disclose obtaining values of *basal metabolic* temperature and *waking* peak flow. However based on the Applicant's specification, in particular page 11 lines 19-24, basal metabolic temperature and waking peak flow are no different from standard values of temperature and peak flow other than *when* the device is used to obtain these values. As such the specific types of temperature and peak flow claimed by the Applicant appears to be directed to intended use, specifically when to use the device. Therefore although not expressed the

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apparatus of Ross would therefore be capable of obtaining such values by merely using the device at the appropriate time, in this case after a subject has just awoken.

Modified Ross also discloses the following claim limitations:

11. The apparatus of claim 10 further comprising a connector for transmitting the measured values to a remote location (Ross paragraph [0136], [0160], and [0161] indicating an electrical connector to transmit signals).

12. The apparatus of claim 10 further comprising a wireless means for transmitting the measured values to a remote location (Ross paragraphs [0147], [0160], and [0161] indicating wireless transmission).

13. The apparatus of claim 10 wherein said fluid channel has at least one continuous wall extending from the mouthpiece to an exit (Fig. 23 the fluid channel extends continuously from the mouthpiece to apertures located at the end of the channel as disclosed in paragraph [0114] and [0117]).

Claim 14 is rejected for substantially the same reasoning as claim 10.

15. The apparatus of claim 14 further comprising a memory storing measured values of basal metabolic temperature, peak flow and saliva acidity (Ross Fig. 1F memory 80 as disclosed in paragraph [0051] and [0152] for storing sensed physiological parameters for future access).

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16. The apparatus of claim 14 further comprising an electrical connector (Ross paragraph [0136], [0160], and [0161] indicating an electrical connector to transmit signals).

Claims 17-19 are rejected as being disclosed in Ross paragraphs [0141] - [0143] and [0179] disclosing a computation module attached to the body and connected to the respiratory analyzer for obtaining cardiac output related parameters including heart rate and pulse oximetry values. Pulse oximetry is usually associated with measuring values from a fingertip.

20. The apparatus of claim 19 further comprising a memory storing measured values of heart rate and percentage of oxygen saturation (Ross Fig. 1F memory 80 as disclosed in paragraph [0051] and [0152] for storing sensed physiological parameters for future access).

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

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however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bobby Soriano whose telephone number is (571)270-7030. The examiner can normally be reached on Monday thru Friday, 10:30am to 6:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry Johnson III can be reached on 571-272-4768. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Bobby Soriano/  
Examiner, Art Unit 3769

/Henry M. Johnson, III/  
Supervisory Patent Examiner, Art Unit  
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May 25, 2010